UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,004	07/25/2003	Abraham Pinter	ABX-PHRI CON	3975

1473 7590 06/29/2006

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,004	PINTER ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,[redacted],10-16,19,20,22-25,27,28,31-33,35-41,43-46,52,53,55,61-72,74,78,85,88,90.91,94,97,102,104,107,109-112,114-116,118-123,133 and 135-139.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,[redacted],10-16,19,20,22-25,27,28,31-33,35-41,43-46,52,53,55,61-72,74,78,85,88,90.91,94,97,102,104,107,109-112,114-116,118-123,133 and 135-139.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 10-16, 22, and 23, drawn to an isolated antibody that binds the V1/V2 loop and is dependent on the presence of a sequence in the V1 loop, classified in class 530, subclass 387.1.

If Applicant elects Group I, then they must elect one hybridoma cell line from claim 15 or 22.

II. Claims 19 and 20, drawn to a hybridoma cell line, classified in class 435, subclass 326.

III. Claims 24, 25, and 27, drawn to a nucleic acid, classified in class 536, subclass 23.1.

IV. Claims 32, 33, 35-41, drawn to an isolated antibody that binds the V1/V2 loop and is dependent on the presence of a sequence in the V2 loop, classified in class 530, subclass 387.1.

V. Claims 45 and 48, drawn to a nucleic acid of a heavy chain, classified in class 536, subclass 23.1.

VI. Claim 46, drawn to a nucleic acid of a light chain, classified in class 536, subclass 23.1.

VII. Claims 56-59 and 61-68, drawn to an isolated antibody that binds the V1/V2 loop and is dependent on the presence of a sequence in the V3 loop, classified in class 530, subclass 387.1.

VIII. Claims 71 and 74, drawn to a nucleic acid of a heavy chain, classified in class 536, subclass 23.1.

IX. Claim 72, drawn to a nucleic acid of a light chain, classified in class 536, subclass 23.1.

X. Claims 109-112 and 114, drawn to an antibody, classified in class 530, subclass 387.1. If Applicant elects Group X then they must elect one cell lines recited in the claims that produces the antibody.

XI. Claim 115, drawn to a method to treat, classified in class 424, subclass 130.1. If Applicant elects Group XI then they must elect one cell lines recited in the claims that produces the antibody.

XII. Claims 116, 118-120, drawn to a method to prevent, classified in class 424, subclass 130.1. If Applicant elects Group XII then they must elect one cell lines recited in the claims that produces the antibody.

XIII. Claim 133, drawn to a method for identifying a region of gp120 to use as a vaccine, classified in class 435, subclass 5.

XIV. Claims 135-137, drawn to an isolated cell line, classified in class 435, subclass 326.

If applicant elects Group XIV, then they must elect one cell line recited in the claims for examination.

XV. Claim 138, drawn to a transgenic non-human mammal, classified in class 800, subclass 8.

The following claims are generic and will be examined with the indicated group if the Group is elected:

Groups I and II- claim 139

Groups I and IV- claims 53 and 55

Groups I, IV, and VII- claims 69, 70, 85, 88, 90, 91, 94, 97, 102, 104, and 107 and

Groups XI and XII- claims 121-123.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-X, XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different products or different types of products. The antibodies are different from one another by the required binding specificities (V1, V2, V3) or they are drawn to different deposited lines that produce

them. The nucleic acid id different because the NA can be used to probe for other antibodies, not just make the recited antibodies.

Inventions I-X, XIV and XV and XI-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods can be practiced with different antibodies.

Inventions XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different methods different target populations (uninfected vs infected individuals) and different outcomes of the method (treat prevent). The method to identify is not related to the methods of treatment/prevention because the do not have the same steps or outcomes

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. Applicant is reminded that the election of a cell line or antibody is not an election of species but to patentably distinct products

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Myron G. Hill
Patent Examiner
26 June 2006

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600